

**Subpart E—Neurological Surgical Devices**

**§ 882.4030 Skull plate anvil.**

(a) *Identification.* A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

**§ 882.4060 Ventricular cannula.**

(a) *Identification.* A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(b) *Classification.* Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

**§ 882.4100 Ventricular catheter.**

(a) *Identification.* A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

(b) *Classification.* Class II (performance standards).

**§ 882.4125 Neurosurgical chair.**

(a) *Identification.* A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

**§ 882.4150 Scalp clip.**

(a) *Identification.* A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

(b) *Classification.* Class II (performance standards).

**§ 882.4175 Aneurysm clip applicator.**

(a) *Identification.* An aneurysm clip applicator is a device used by the surgeon for holding and applying intracranial aneurysm clips.

(b) *Classification.* Class II (performance standards).

**§ 882.4190 Clip forming/cutting instrument.**

(a) *Identification.* A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

**§ 882.4200 Clip removal instrument.**

(a) *Identification.* A clip removal instrument is a device used to remove surgical clips from the patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

**§ 882.4215 Clip rack.**

(a) *Identification.* A clip rack is a device used to hold or store surgical clips during surgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989; 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

**§ 882.4250 Cryogenic surgical device.**

(a) *Identification.* A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in

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nervous tissue by the application of extreme cold to the selected site.

(b) *Classification*. Class II (performance standards).

### § 882.4275 Dowel cutting instrument.

(a) *Identification*. A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.

(b) *Classification*. Class II (performance standards).

### § 882.4300 Manual cranial drills, burrs, trephines, and their accessories

(a) *Identification*. Manual cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that are used without a power source on a patient's skull.

(b) *Classification*. Class II (performance standards).

### § 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.

(a) *Identification*. Powered compound cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain.

(b) *Classification*. Class II (performance standards).

### § 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.

(a) *Identification*. Powered simple cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.

(b) *Classification*. Class II (performance standards).

### § 882.4325 Cranial drill handpiece (brace).

(a) *Identification*. A cranial drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools that are used on a patient's skull.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

### § 882.4360 Electric cranial drill motor.

(a) *Identification*. An electric cranial drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification*. Class II (performance standards).

### § 882.4370 Pneumatic cranial drill motor.

(a) *Identification*. A pneumatic cranial drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification*. Class II (performance standards).

### § 882.4400 Radiofrequency lesion generator.

(a) *Identification*. A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

(b) *Classification*. Class II (performance standards).

### § 882.4440 Neurosurgical headrests.

(a) *Identification*. A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

### § 882.4460 Neurosurgical head holder (skull clamp).

(a) *Identification*. A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to